5.0 510(k) Summary

FEB 15 2013

1. Sponsor

SpineFrontier, Inc.
500 Cummings Center
Suite 3500
Beverly, MA 01915

Primary Contact: Fredy H. Varela, MSRA, RAC
Telephone: 1- 978-232-3990

Date Prepared: December 14, 2012

2. Device Name and Classification:

Proprietary Names: **SpineFrontier® PedFuse® Pedicle Screw System**

Common/Usual Name: Pedicle Screw Spinal System

Classification Name: Orthosis, Spondylolisthesis Spinal Fixation
Orthosis, Spinal Pedicle Fixation
(21 CFR 888.3070(b)(1)), Class II

Product Code: MNH, MNI

3. Predicate Devices

K092420 – SpineFrontier® KRD1™ Pedicle Screw System
K950099 – Synergy Posterior Spinal System
K992739 – Synthes USS Click-X Variable Axis System
K100605 – Spine Wave MIS Pedicle Screw System
K061591 – Medtronic CD Horizon Spinal System

4. Device Description

The **SpineFrontier® PedFuse® Pedicle Screw System** consists of longitudinal rods, polyaxial screws, tulips, transverse connectors, and instrumentation to facilitate installation of this system.

The PedFuse® Pedicle Screw is offered in multiple screw types, with multiple diameters and lengths to accommodate individual patient needs. PedFuse® Pedicle Screw assemblies consist of the screw, a

tulip, and a washer that secures the tulip to the screw and also serves as the saddle for the longitudinal rod. The tulip and screw designs allow the screw to have a polyaxial rotation relative to the tulip. A locking cap is placed on top of the pedicle screw assembly to secure the position of the implant and to retain the longitudinal rod.

The PedFuse® Pedicle Screw assembly serves as the central fixation device to which various rods and cross connectors are secured to provide desired fixation.

Longitudinal rods are provided in two configurations, straight and lordotic, have a fixed diameter (5.5mm), and vary by length.

Cross connector assemblies are provided in multiple configurations, varying by length. Cross connectors are used to provide additional fixation support.

For percutaneous, minimally invasive surgical (MIS) procedure, extended Respond tulips and bulleted rods are introduced. Instruments for the MIS technique are also used.

The **SpineFrontier® PedFuse® Pedicle Screw System** components are fabricated from medical grade titanium conforming to ASTM F-136 specifications.

5. Intended Use

The **SpineFrontier® PedFuse® Pedicle Screw System** is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (Pseudarthrosis).

In addition, the **SpineFrontier® PedFuse® Pedicle Screw System** is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine.

When used in a percutaneous approach with MIS instrumentation, the **SpineFrontier® PedFuse® Pedicle Screw System** is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute instabilities or deformities of the thoracic, lumbar, and sacral

spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, failed previous fusion (Pseudarthrosis) and severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine.

6. Technological Characteristics and Substantial Equivalence Determination

The **SpineFrontier® PedFuse® Pedicle Screw System** was shown to be substantially equivalent to predicate devices through comparison of indications for use, function, operating principles and materials.

The **SpineFrontier® PedFuse® Pedicle Screw System** was evaluated in accordance with FDA Document, Guidance for Industry and FDA Staff – Spinal System 510(k)s, May 3, 2004, and has been found to meet criteria defined in the guidance document; and has been demonstrated to be substantially equivalent to predicate devices in terms of indications for use, function, materials and performance (mechanical testing). Clinical data was not required for this device.

Mechanical testing includes performance assessments per the following recognized test methods:

- ASTM Standard F1717, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 15, 2013

SpineFrontier, Incorporated
% Fredy H. Varela, MSRA, RAC
Regulatory Affairs Specialist
500 Cummings Center, Suite 3500
Beverly, Massachusetts 01915

Re: K123164
Trade/Device Name: SpineFrontier® PedFuse® Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: December14, 2012
Received: December 18, 2012

Dear Mr. Varela:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if Known): K123164

Device Name: SpineFrontier® PedFuse® Pedicle Screw System

Indications For Use:

The **SpineFrontier® PedFuse® Pedicle Screw System** is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (Pseudarthrosis).

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Prescription Use: X **OR** **Over-The-Counter Use:** _____
(Part 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin O'Neill

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123164